# **Complete Summary**

#### **GUIDELINE TITLE**

2002 national guideline on the management of balanitis.

# BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of balanitis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [19 references]

# **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

# **SCOPE**

#### DISEASE/CONDITION(S)

Balanitis

**GUIDELINE CATEGORY** 

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Infectious Diseases Urology

INTENDED USERS

**Physicians** 

## GUI DELI NE OBJECTI VE(S)

To present a national guideline on the management of balanitis

#### TARGET POPULATION

Male patients in the United Kingdom with balanitis

#### INTERVENTIONS AND PRACTICES CONSIDERED

# Assessment/Diagnosis

- 1. Assessment of clinical features
- 2. Sub-preputial swab for Candida and bacterial culture
- 3. Urinalysis for glucose
- 4. Culture for Herpes simplex
- 5. Dark ground examination for spirochaetes and syphilis serology
- 6. Culture for Trichomonas vaginalis
- 7. Screening for other sexually transmitted infections, such as Chlamydia trachomatis infection/non specific urethritis
- 8. Biopsy

# Management/Treatment

- 1. General advice and patient education
- 2. Treatment for Candidal balanitis
  - Clotrimazole cream 1%
  - Miconazole cream 2%
  - Fluconazole 150 mg
  - Nystatin cream 100 000 units/g
  - Topical imidazole with 1% hydrocortisone
- 3. Treatment for anaerobic infection
  - Metronidazole 400 mg
  - Co-amoxiclav 375 mg
  - Clindamycin cream
- 4. Treatment for aerobic infection depending on the sensitivities of the organism isolated
- 5. Treatment for lichen sclerosus
  - Topical steroids (clobetasol propionate or betamethasone valerate)
  - Circumcision
  - Surgical treatment (meatoplasty, urethroplasty or laser vaporization)
- 6. Treatment for Zoon's (plasma cell) balanitis
  - Circumcision
  - Topical steroid preparations (e.g., Trimovate cream)
  - Carbon dioxide laser
- 7. Treatment of Erythroplasia of Queyrat
  - Surgical excision
  - Fluorouracil cream 5%
  - Laser resection
  - Cryotherapy
- 8. Treatment of Bowen's disease
  - Local simple excision

- Fluorouracil cream
- Laser resection
- 9. Treatment of Bowenoid papulosis
  - Local excision
  - Laser ablation
- 10. Treatment for circinate balanitis
  - Hydrocortisone cream 1%
  - Treatment of any underlying infection
  - More potent topical steroids as required
- 11. Treatment of fixed drug eruptions
  - No treatment
  - Topical (e.g., hydrocortisone 1%) or systemic steroids
- 12. Treatment for irritant/allergic balanitides
  - Avoidance of precipitants
  - Emollients- aqueous cream
  - Hydrocortisone 1%
- 13. As appropriate, screening for sexually transmitted infections in patients and partners
- 14. Follow up

#### MAJOR OUTCOMES CONSIDERED

Not stated

#### METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers performed a Medline (U.S. National Library of Medicine) for the period 1966 to 2000, using the keywords "balanitis", "balanoposthitis", "penile dermatoses", and specific terms relevant to each condition. They also searched the Cochrane Library databases.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence:

Ιa

• Evidence obtained from meta-analysis of randomised controlled trials

Ιb

Evidence obtained from at least one randomised controlled trial

Пa

• Evidence obtained from at least one well designed controlled study without randomisation

Hb

 Evidence obtained from at least one other type of well designed quasiexperimental study

 $\Pi\Pi$ 

• Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

١V

• Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The revision process commenced with authors being invited to modify and update their 1999 guidelines. These revised versions were posted on the website for a 3 month period and comments invited. The Clinical Effectiveness Group and the authors concerned considered all suggestions and agreed on any modifications to be made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

# Grading of Recommendations:

## A (Evidence Levels Ia, Ib)

 Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

## B (Evidence Levels IIa, IIb, III)

• Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

## C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

# DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial versions of the guidelines were sent for review to the following:

- Clinical Effectiveness Group (CEG) members
- Chairs of UK Regional GU Medicine Audit Committees who had responded to an invitation to comment on them
- Chair of the Genitourinary Nurses Association (GUNA)
- President of the Society of Health Advisers in Sexually Transmitted Diseases (SHASTD)
- Clinical Effectiveness Committee of the Faculty of Family Planning and Reproductive Health Care (FFP).

Comments were relayed to the authors and attempts made to reach a consensus on points of contention with ultimate editorial control resting with the Clinical Effectiveness Group. Finally, all the guidelines were ratified by the councils of the two parent societies.

# RECOMMENDATIONS

Definitions of the levels of evidence (I-IV) and grades of recommendation (A-C) are repeated at the end of the "Major Recommendations" field.

# Diagnosis

Balanitis is a descriptive term covering a variety of unrelated conditions, the appearances of which may be pathognomonic.

The following investigations (refer to original guideline document for a flow chart for management of non specific balanitis) are intended to aid diagnosis in cases of uncertainty.

- Sub-preputial swab for Candida and bacterial culture: should be undertaken in most cases to exclude an infective cause or superinfection of a skin lesion.
- Urinalysis for glucose: appropriate in most cases but especially if candidal infection is suspected.
- Culture for Herpes simplex: if ulceration/fissures present.
- Dark ground examination for spirochaetes and Syphilis serology: if an ulcer is present.
- Culture for Trichomonas vaginalis: particularly if a female partner has an undiagnosed vaginal discharge.
- Screening for other sexually transmitted infections: particularly screening for Chlamydia trachomatis infection/non specific urethritis if a circinate-type balanitis is present.
- Biopsy: if the diagnosis is uncertain and the condition persists. (Arumainayagam & Sumathipala, 1990; Hillman et al., 1992)

# Management

Balanitis is a clinical diagnosis and covers a range of heterogeneous conditions. The recommendations for management are therefore given on an individual basis.

## General advice

- Saline bathing with a weak salt solution twice daily while symptoms persist.
- Avoid soaps while inflammation present (Birley et al., 1993).
- Advise about effect on condoms if creams are being applied.
- Patients should be given a detailed explanation of their condition with particular emphasis on the long-term implications for their health (and that of their partner where a sexually transmissible agent is found).

## Infective balanitides

Candidal balanitis

#### <u>Diagnosis</u>

- Symptoms: erythematous rash, with soreness and/or itch
- Appearance: blotchy erythema with a small papules which may be eroded, or dry dull red areas with a glazed appearance
- Sub-preputial culture

## <u>Treatment</u>

# Recommended regimens

- Clotrimazole cream 1% (Stary et al., 1996) (level of evidence Ib, grade of recommendation A).
- Miconazole cream 2% (Forster & Harris, 1986) (IIa, B)
   Apply twice daily until symptoms have settled.

# Alternative regimens

- Fluconazole 150 mg immediately (stat) orally (Stary et al., 1996) (lb, A) if symptoms severe.
- Nystatin cream (Forster & Harris, 1986) 100 000 units/g, if resistance suspected, or allergy to imidazoles (IIa. B).
- Topical imidazole with 1% hydrocortisone if marked inflammation is present (IV, C).

# Sexual partners

There is a high rate of Candidal infection in sexual partners, who should be offered screening.

# Follow up

Not required unless symptoms and signs are particularly severe or an underlying problem is suspected.

Anaerobic infection (Ewart et al., 1982)

#### Diagnosis

- Symptoms: foul smelling discharge, swelling, and inflamed glands.
- Appearance: preputial oedema, superficial erosions, inguinal adenitis. Milder forms also occur.
- Sub-preputial culture (to exclude other causes).

## Treatment

# Recommended regimen

Metronidazole 400 mg twice daily for 1 week (IV, C).
 The optimum dosage schedule for treatment is unknown.

# Alternative regimen

- Co-amoxiclav 375 mg three times daily for 1 week.
- Clindamycin cream applied twice daily until resolved.

These treatments have not been assessed in clinical trials (IV, C).

## Aerobic infection

# **Diagnosis**

# Sub-preputial culture

• Streptococci group A, Staphylococcus aureus, and Gardnerella vaginalis have all been reported as causing balanitis. Other organisms may also be involved.

#### Treatment

Depends on the sensitivities of the organism isolated.

- Herpes simplex: Diagnosis and treatment as per specific guidelines.
- Trichomonas vaginalis: Diagnosis and treatment as per specific guidelines.
- Syphilis: Diagnosis and treatment as per specific guidelines.
- Specific balanitides

These may be recognized either by clinical appearance, or preferably confirmed on biopsy.

Lichen sclerosus (Previously known as lichen sclerosis et atrophicus and balanitis xerotica obliterans)

#### Diagnosis

- Typical appearance: white plaques on the glans, often with involvement of the prepuce. There may be haemorrhagic vesicles and, rarely, blisters and ulceration. The prepuce may become phimotic, and the meatus may be thickened and narrowed.
- Biopsy: this initially shows a thickened epidermis which then becomes atrophic with follicular hyperkeratosis. This overlies oedema and loss of the elastin fibers, with an underlying perivascular lymphocytic infiltrate. Biopsy is the definitive diagnostic procedure.

## **Treatment**

#### Recommended regimens

 Potent topical steroids steroids (Dahlman-Ghozlan, Hedblad, & von Krogh, 1999) (e.g., clobetasol propionate or Betamethasone valerate) applied once daily until remission, then gradually reduced. Intermittent use (e.g., once weekly) may be required to maintain remission (IV, C).

#### Alternative treatment

- Circumcision (Liatsikos et al., 1997) if phimosis develops. (IV, C)
- Surgery for meatal stenosis (meatoplasty, urethroplasty or laser vaporization have been used (IV, C).

Nota Bene: These procedures may be required for specific complications, but treatment of the underlying skin disease will still be required.

## Follow up

- Patients requiring potent topical steroids for disease control should be followed up regularly.
- The frequency of follow up will depend on the disease activity and symptoms of the patient, but all patients should be reviewed by a doctor at least annually in view of the small risk (less than 1%) of malignant transformation. (Bernstein, Forgaard, & Miller, 1986)
- In addition, patients should be advised to contact the general practitioner or clinic if the appearances change (IV, C).
- Zoon's (plasma cell) balanitis

# Diagnosis

- Typical appearance: well circumscribed orange-red glazed areas on the glans with multiple pinpoint redder spots "cayenne pepper spots". This may be similar to Erythroplasia of Queyrat which is premalignant and biopsy is advisable.
- Biopsy: epidermal atrophy, loss of rete ridges, lozenge keratinocytes, and spongiosis, together with a predominantly plasma cell infiltrate subepidermally.

#### Treatment

## Recommended regimens

- Circumcision: this has been reported to lead to the resolution of lesions (Kumar et al., 1995) (IV, C).
- Topical steroid preparations: with or without added antibacterial agents; e.g., Trimovate cream, applied once or twice daily. (Oates, 1990) There is no evidence on effectiveness (IV, C).
- Carbon dioxide laser: this has been used to treat individual lesions (Boon, 1988) (IV, C).

#### Follow up

• Dependent on clinical course and treatment used, especially if topical steroids are being used long term.

- In cases of diagnostic uncertainty penile biopsy should be performed prior to discontinuing follow up to exclude Erythroplasia of Queyrat.
- Erythroplasia of Queyrat

## **Diagnosis**

- Typical appearance: red, velvety, well circumscribed area on the glans.
   May have raised white areas, but if indurated suggests frank squamous cell carcinoma.
- Biopsy: essential squamous carcinoma in situ.

#### <u>Treatment</u>

# Recommended regimen

• Surgical excision: local excision is usually adequate and effective (Mikhail, 1980) (IV, C).

# Alternative regimens

- Fluorouracil cream 5% (Goette, Elgart, & DeVillez, 1975) (IV, C).
- Laser resection (Boon, 1988) (IV, C).
- Cryotherapy (Sonnex et al., 1982) (IV, C).

# Follow up

Obligatory because of the possibility of recurrence. Minimum of annual appointments.

Other premalignant conditions

Bowen's disease: This is also cutaneous carcinoma in situ and presents as a scaly, discrete, erythematous plaque. Up to 20% will develop into frank squamous carcinoma. Biopsy is essential. Treatment is by local simple excision, although fluorouracil cream and laser resection have been used. Follow up is essential (IV, C).

Bowenoid papulosis: Another form of carcinoma in situ, this is linked to human papilloma virus (HPV) infection particularly with type 18. Lesions range from discrete papules to plaques. Treatment options include local excision and laser ablation, but some lesions will regress spontaneously (IV, C).

The premalignant conditions form a continuum with Penile Intraepithelial Neoplasia (PIN), but vary in clinical presentation and natural history. (Schellhammer et al., 1992)

Circinate balanitis

# <u>Diagnosis</u>

- Typical appearance: grayish white areas on the glans which coalesce to form "geographical" areas with a white margin. It may be associated with other features of Reiter's syndrome but can occur without these symptoms.
- Biopsy: spongiform pustules in the upper epidermis, similar to pustular psoriasis.
- Screening for sexually transmitted infections.

#### Treatment

# Recommended regimen

- Hydrocortisone cream 1% applied twice daily for symptomatic relief (Oates, 1990) (IV, C).
- Treatment of any underlying infection.

# Alternative regimens

- In some cases treatment may not be required.
- More potent topical steroids may be required in some cases.

# Sexual partners

If a sexually transmitted infection is diagnosed the partner(s) should be treated as per the appropriate protocol.

# Follow up

- May be needed for persistent symptomatic lesions.
- Any associated findings should be followed up as per appropriate guidelines.
- Fixed drug eruptions

# **Diagnosis**

- Typical appearance: variable but lesions are usually well demarcated and erythematous, but can be bullous with subsequent ulceration.
- History: a drug history is essential, as is a history of previous reactions. Common precipitants include tetracyclines, salicylates, phenacetin, phenolphthalein, and some hypnotics.
- Rechallenge: this can confirm the diagnosis.

# **Treatment**

- Not essential.
- Occasionally topical steroids: e.g., 1% hydrocortisone applied twice daily until resolution (Braun-Falco et al., 1991) (IV, C).
- Rarely systemic steroids may be required if the lesions are severe.

#### Follow up

- Not required after resolution.
- Patients should be advised to avoid the precipitant.
- Irritant/allergic balanitides

## **Diagnosis**

- Typical appearance: very variable. Appearances range from mild erythema to widespread oedema of the penis.
- History: symptoms have been associated with a history of atopy or more frequent genital washing with soap. In a very small number of cases a history of a precipitant may be obtained.
- Patch tests: useful in the small minority in whom true allergy is suspected.
- Biopsy: may show non-specific inflammation.

#### Treatment

# Recommended regimen

- Avoidance of precipitants, especially soaps. (Birley et al., 1993)
- Emollients: Aqueous cream: applied as required and used as a soap substitute. (Birley et al., 1993)
- Hydrocortisone 1% applied once or twice daily until resolution of symptoms (IV, C).

#### Follow up

Not required, although recurrent problems are common and the patients need to be informed of this.

Other skin conditions

A range of other skin conditions may affect the glans penis. These include psoriasis, lichen planus, seborrhoeic dermatitis, pemphigus, and dermatitis artefacta. (Edwards, 1996)

## **Definitions**

The following rating scheme was used for major management recommendations.

Levels of Evidence

Ιa

• Evidence obtained from meta-analysis of randomised controlled trials

Ιb

• Evidence obtained from at least one randomised controlled trial

Пa

 Evidence obtained from at least one well designed controlled study without randomisation

Hb

 Evidence obtained from at least one other type of well designed quasiexperimental study

 $\Pi\Pi$ 

• Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV

• Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grading of recommendations

A (Evidence levels Ia, Ib)

 Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence levels IIa, IIb, III)

 Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

CLINICAL ALGORITHM(S)

A flow chart for management of nonspecific balanitis is provided in the guideline document.

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Appropriate diagnosis and management of balanitis

POTENTIAL HARMS

Not stated

# QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

Although recommended as alternative regimen for anaerobic infection, Coamoxiclav and clindamycin cream have not been assessed in clinical trials.

# IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

The Clinical Effectiveness Group reminds the reader that guidelines in themselves are of no use unless they are implemented systematically. The following auditable outcome measures are provided:

 Biopsy where balanitis persists for more than 6 weeks despite simple treatment. Target 80%.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

**Getting Better** 

IOM DOMAIN

Effectiveness Patient-centeredness

# IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of balanitis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [19 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2002)

GUI DELI NE DEVELOPER(S)

Association for Genitourinary Medicine - Medical Specialty Society Medical Society for the Study of Venereal Diseases - Disease Specific Society

SOURCE(S) OF FUNDING

Not stated

**GUI DELI NE COMMITTEE** 

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Ahmed-Jushuf; Jan Welch; Mark FitzGerald; Janet Wilson

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflict of Interest: None

**GUIDELINE STATUS** 

This is the current release of the guideline. This guideline updates a previously released version.

An update is not in progress at this time.

**GUIDELINE AVAILABILITY** 

Electronic copies: Available in HTML format from the <u>Association for Genitourinary Medicine (AGUM) Web site</u>. Also available in Portable Document Format (PDF) from the Medical Society for the Study of Venereal Diseases (MSSVD) Web site.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• UK national guidelines on sexually transmitted infections and closely related conditions. Introduction. Sex Transm Infect 1999 Aug; 75(Suppl 1): S2-3.

Electronic copies: Available in Portable Document Format (PDF) from the <u>Medical Society for the Study of Venereal Diseases (MSSVD) Web site</u>.

The following is also available:

 Revised UK national guidelines on sexually transmitted infections and closely related conditions 2002. Sex Transm Infect 2002;78:81-2

Print copies: For further information, please contact the journal publisher, <u>BMJ</u> <u>Publishing Group</u>.

#### PATIENT RESOURCES

None available

#### **NGC STATUS**

This summary was completed by ECRI on December 8, 2000. The information was verified by the guideline developer on January 12, 2001. This summary was updated on August 5, 2002.

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# FirstGov

